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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,673	02/23/2004	Conceicao Minetti	13564-105004US3	3568
65989	7590	02/15/2008	EXAMINER	
KING & SPALDING			DEVI, SARVAMANGALA J N	
1185 AVENUE OF THE AMERICAS				
NEW YORK, NY 10036-4003			ART UNIT	PAPER NUMBER
			1645	
			NOTIFICATION DATE	DELIVERY MODE
			02/15/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[usptomailnyc@kslaw.com](mailto:usptomailnyc@kslaw.com)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/785,673	MINETTI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 November 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 16-21 and 27-40 is/are pending in the application.
  - 4a) Of the above claim(s) 27-30 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16-21 and 31-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

**1)** Acknowledgment is made of Applicants' amendment filed 11/29/07 in response to the non-final Office Action mailed 05/29/07.

### **Status of Claims**

**2)** Claims 16, 17, 19-21 and 31-40 have been amended via the amendment filed 11/29/07.  
Claims 16-21 and 27-40 are pending.  
Claims 16-21 and 31-40 are under examination.

### **Objection(s) Withdrawn**

**3)** The objection to the oath/declaration made in paragraph 7 of the Office Action mailed 05/29/07 is withdrawn in light of Applicants' submission of oath/declaration filed 01/14/08.

**4)** The objection to the specification made in paragraph 8 of the Office Action mailed 05/29/07 is withdrawn in light of Applicants' amendment to the specification.

**5)** The objection to claim 31 made in paragraph 15 of the Office Action mailed 05/29/07 is withdrawn in light of Applicants' amendment to the claim.

### **Rejection(s) Withdrawn**

**6)** The rejection of claim 19 and those dependent therefrom, and claims 32-40 made in paragraph 10 of the Office Action mailed 05/29/07 under 35 U.S.C. § 101 as being directed to non-statutory subject matter, is withdrawn in light of Applicants' amendment to claim 19.

**7)** The rejection of claims 32-40 made in paragraph 12 of the Office Action mailed 05/29/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to the claims.

**8)** The rejection of claim 16 made in paragraph 14(a) of the Office Action mailed 05/29/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn upon further consideration.

**9)** The rejection of claim 20 made in paragraph 14(b) of the Office Action mailed 05/29/07

under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**10)** The rejection of claim 31 made in paragraph 14(d) of the Office Action mailed 05/29/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

**11)** The rejection of claim 16 made in paragraph 14(e) of the Office Action mailed 05/29/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

### **Rejection(s) under 35 U.S.C. § 101 Maintained**

**12)** 35 U.S.C. § 101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

**13)** The rejection of claims 32-40 made in paragraph 10 of the Office Action mailed 05/29/07 under 35 U.S.C. § 101 as being directed to non-statutory subject matter, is maintained for reasons set forth therein and herein below.

Applicants contend that claims 32-40 are directed to man-made nucleic acid molecules corresponding to man-made pneumolysin sequences made according to the methods set forth in Example 5 and Table 6, and therefore are patentable under 35 U.S.C. § 101.

Applicants' argument has been carefully considered, but is not persuasive. What are described in Example 5, Table 6 and other parts of the specification are recombinant nucleic acid molecules encoding the modified pneumolysin polypeptides pNVJ1, pNVJ20, pNVJ22, pNVJ45, pNVJ56, pNV103, pNV207, pNV111, and pNV211. Claims 32-40, as amended, fail to distinguish over a pneumolysin nucleic acid molecule having one or more spontaneous mutations therein said nucleic acid molecule comprised within a pneumococcus bacterium as it exists naturally. The rejection stands.

### **New Matter Rejection Maintained**

**14)** The rejection of claim 17 and the dependent claims 18-21 and 31 made in paragraph 11 of the Office Action mailed 05/29/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is maintained for the reason set forth therein and herein below.

It is noted that Applicants have addressed the issue raised with the generic limitation ‘recombinant molecule’. However, the new limitation ‘non-coding sequence changes thereof’ identified therein continues to be a part of the claim. Applicants have not addressed the new matter issue raised with regard to the new limitation ‘non-coding sequence changes thereof’. The rejection stands.

### **35 U.S.C. § 112, Second Paragraph Rejection(s) Maintained**

**15)** The rejection of claim 17 made in paragraph 14(c) of the Office Action mailed 05/29/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein and herein below.

Applicants point to page 33, line 30 to page 34, line 4 of the specification and state that one of ordinary skill in the art would understand that this language refers to nucleotide mutations that lead to the same translated amino acid sequence.

Applicants’ argument has been considered, but is not persuasive. The part of the specification pointed to by Applicants does not even recite the limitation: ‘non-coding sequence changes thereof’ let alone define it as being equivalent in scope to nucleotide mutations that lead to the same translated amino acid sequence. Without a clear definition, one of skill in the art would not be able to understand the scope of the claims and the metes and bounds of the phrase. The rejection stands.

**16)** The rejection of claims 18-21 and 31 made in paragraph 14(f) of the Office Action mailed 08/29/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein and herein below.

### **New Rejection(s) Necessitated by Applicants’ Amendment**

#### **Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)**

**17)** Claims 19-21 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 19-21, as amended, include the new limitations: ‘genetically engineered’ microorganism and/or ‘genetically engineered cell’. Applicants state that support for the amendment

is generally found throughout the specification. Applicants submit that the specification at page 30, line 27 to page 33, line 1 provides examples of some of the genetic engineering techniques contemplated by the invention, and that the paragraph beginning at line 2 of page 33 describes some of the various expression hosts contemplated by the invention providing support for a ‘microorganism’ and a ‘cell’ as recited in the instant claims. However, these parts of the specification do not provide descriptive support for the now recited ‘genetically engineered’ microorganism and/or ‘genetically engineered cell’. These parts of the specification describe prokaryotic and eukaryotic expression host cells, *E. coli* transformed with plasmids or vectors, yeasts, insect, animal, human and plant cells as suitable eukaryotic cells, preferred vectors or plasmids, fusion constructs, and a microorganism transformed by a vector. The limitations ‘genetically engineered’ microorganism and ‘genetically engineered cell’ do not appear in the instant specification. Therefore, the above-identified limitations in claims 19-21 are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

### **35 U.S.C. § 112, Second Paragraph Rejection(s) Maintained**

**18)** The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

**19)** Claims 16-21 and 31-40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) For the purpose of distinctly claiming the subject matter, in claim 20, it is suggested that Applicants replace the limitations: ‘microorganism or .... cell is selected from the group consisting of’ with the limitations --microorganism is selected from the group consisting of bacteria and yeast and the .... cell is selected from the group consisting of mammalian cells and insect cells--.

(b) Claims 32-40 are indefinite and/or incorrect in the limitation: ‘nucleic acid molecule encoding the nucleic acid sequence’. For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the above-identified limitation with the phrase --nucleic acid molecule encoding the modified pneumolysin polypeptide . . .--.

(c) In the amended claim 16, for the purpose of distinctly claiming the subject matter, it is suggested that Applicants insert the limitation --of SEQ ID NO: 3-- following the limitation ‘195,’ in line 5 and ‘257’ in 7 of the claim.

(d) Claims 18-21 and 31, which depend from claim 16, is also rejected as being indefinite because of the indefiniteness identified above in the base claim.

### **Objection to Claim(s)**

**20)** Claim 20 is objected to for including extra spaces in line 1 before and after the limitations ‘genetically’, ‘engineered’ and ‘microorganism’.

### **Remarks**

**21)** Claims 16-21 and 31-40 stand rejected.

**22)** Applicants’ amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**23)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**24)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**25)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached on (571) 272-0898.

/S. Devi, Ph.D./  
Primary Examiner  
Art Unit 1645

February, 2008